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10/520,533	01/06/2005	Axel Jentzsch	263530US0PCT	9639

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EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/520,533	JENTZSCH ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____is/ are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-17 are presented for examination.

Applicant's Amendment and Interview Summary filed November 16, 2007 have each been received and entered into the present application.

Claims 1-17 remain pending and under examination.

Upon reconsideration of the present claims, and those of copending U.S. Patent Application No. 10/515,636, the obviousness-type double patenting rejection as set forth at pages 2-3 of the previous Office Action dated June 22, 2007 has been hereby withdrawn. The instant claims require a solid phase of ascorbic acid salts in the dispersant, which necessarily implies the physical property of a suspension, i.e., where there is a liquid phase and a *solid* phase (of particles that are of sufficient size for sedimentation). However, the copending claims of the '636 application contain both a water and oil phase, which implies the physical property of an emulsion, i.e., wherein there are two liquid phases (a water and oil phase) that are immiscible (see, e.g., copending claim 9). In other words, there is no solid phase indicative of a suspension in the claims of the '636 application and, thus, the claims do not appear to encompass obvious variants. Additionally, for these same reasons, an obviousness-type double patenting rejection has not been made over the claims of U.S. Patent Application No. 10/586,776.

Applicant's arguments, filed November 16, 2007, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement

(New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 7-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Independent claim 1 is directed to a suspension comprising at least one oxidation-sensitive substance selected from the group consisting of carotenoids, retinoids and unsaturated fatty acids and solid particles of one or more salts of ascorbic acid in a dispersant, wherein said one or more salts of ascorbic acid are insoluble. Present claim 10 defines a process for preparing said suspension. Present claim 11 defines a method for reducing oxidation of one or more oxidation-sensitive substances and present claim 14 defines a method for reducing oxidation of a human food, animal feed, etc. using said suspension.

In particular, the specification as originally filed fails to provide adequate written description for (1) the genus of retinoids (claim 1) or (2) the genus of unsaturated fatty acids (claim 1).

Regarding the requirement for adequate written description of chemical entities, Applicant's attention is directed to the MPEP §2163. In particular, *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plan for obtaining the claimed chemical invention." *Eli Lilly*, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for *Examination of Patent Applications* under the 35 U.S.C. 112.1 "Written Description" Requirement ("*Guidelines*"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of

sufficiently detailed, relevant identifying characteristics," including, *inter alia*, "functional characteristics when coupled with a known or disclosed correlation between function and structure..." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 316, 1324-25 (Fed. Cir. 2002) (quoting *Guidelines*, 66 Fed. Reg. at 1106 (emphasis added)). Moreover, although *Eli Lilly* and *Enzo* were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle & Co.*, 249 Supp. 2d 216, 225 (W.D.N.Y. 2003).

Applicant's present claim 1 reads upon the use of a retinoid compound as the oxidation-sensitive substance to be included in the recited suspension preparation. With regard to the claimed genus of "retinoids", Applicant defines the genus at p.3, l.23-32 of the instant specification to include vitamin A alcohol (retinol), its derivatives such as vitamin A aldehyde (retinal), vitamin A acid (retinoic acid) and vitamin A esters (for example retinyl acetate, retinyl propionate and retinyl palmitate).

While such disclosure clearly provides written support for the species of retinoids specifically named (i.e., retinol, retinal, retinoic acid, retinyl acetate, retinyl propionate, or retinyl palmitate), it fails to provide adequate written support for the use of other retinoid compounds, particularly in view of the fact that Applicant further defines the genus as including retinoid "derivatives" and "esters" as stated at l.24-26 of p.3 of the disclosure. Applicant has failed to provide any structural characteristics, chemical formula, name(s) or physical properties of the other retinoid compounds intended to be encompassed by the claimed genus that Applicant was actually in possession of, and intended to be used within the context of the present invention, at the time of the present invention. Accordingly, such disclosure, does not provide a teaching of what compounds other than retinol, retinal, retinoic acid, retinyl acetate, retinyl propionate, or retinyl palmitate would be considered within the scope of the genus "retinoids" such that one of ordinary skill in the art would have been able to readily identify the scope of those compounds encompassed by the genus "retinoids" aside from those explicitly identified in the instant disclosure.

Further, the fact that Applicant has defined the genus of "retinoids" as including "derivatives"

and "esters" of vitamin A further supports the instant conclusion of a lack of written description with regard to the claimed genus of "retinoids". Though it may be construed that the fact that the retinoid compound may be a "derivative" or "ester" of vitamin A (see, e.g., p.3, l.24-26) and, thus, is based upon or derived from vitamin A *per se* implies some sort of chemical or structural characteristic sufficient to fulfill the written description requirement of 35 U.S.C. 112, first paragraph, it is herein noted that Applicant has failed to describe in any certain terms the degree of derivation or structural similarity that a compound may have to the parent vitamin A compound and still be considered within the scope of those retinoid compounds intended for use by Applicant. The mere fact that the only chemical or structural characteristic of the compound is that it is based upon or derived from vitamin A, wherein the degree of similarity or derivation from vitamin A is herein undefined in the accompanying specification, is not sufficient to provide an adequate description of the genus of compounds intended by Applicant for use in the present invention. In the absence of such description, Applicant's limitation to the genus of "retinoids" is not sufficiently supported by the present disclosure in such a way as to satisfy the written description requirement of 35 U.S.C. 112, first paragraph.

Moreover, Applicant's present claim 1 also reads upon the use of an unsaturated fatty acid compound as the oxidation-sensitive substance to be included in the recited suspension preparation. With regard to the claimed genus of "unsaturated fatty acids", Applicant defines the genus at p.3, l.34-36 of the instant specification, stating, "Examples of unsaturated fatty acids are undecylenic acid, palmitoleic acid, oleic acid, linoleic acid, linolenic acid, arachidonic acid, eicosapentaenoic acid, docosahexaenoic acid."

While such exemplary disclosure clearly provides written support for the species of unsaturated fatty acids specifically named (i.e., undecylenic acid, palmitoleic acid, oleic acid, linoleic acid, linolenic acid, arachidonic acid, eicosapentaenoic acid, docosahexaenoic acid), it fails to provide adequate written support for the use of other unsaturated fatty acid compounds. Applicant has failed to provide any limiting definition, such as by providing structural characteristics, chemical formula, name(s) or physical

properties, of the other unsaturated fatty acid compounds intended to be encompassed by the claimed genus that Applicant was actually in possession of, and intended to be used within the context of the present invention, at the time of the present invention. Accordingly, such disclosure does not provide a teaching of what compounds other than undecylenic acid, palmitoleic acid, oleic acid, linoleic acid, linolenic acid, arachidonic acid, eicosapentaenoic acid and docosahexaenoic acid would be considered within the scope of the genus "unsaturated fatty acids" such that one of ordinary skill in the art would have been able to readily identify the scope of those compounds encompassed by the genus "unsaturated fatty acids" aside from those explicitly identified in the instant disclosure.

Please reference MPEP §2163 recites, "The written description requirement for a claimed genus may be satisfied through sufficient description of a *representative number of species* by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the Applicant was in possession of the claimed genus." See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

At best, Applicant has demonstrated the specific species of retinol, retinal, retinoic acid, retinyl acetate, retinyl propionate, or retinyl palmitate in support of the genus of "retinoids" as claimed and the specific species of undecylenic acid, palmitoleic acid, oleic acid, linoleic acid, linolenic acid, arachidonic acid, eicosapentaenoic acid and docosahexaenoic acid in support of the genus of "unsaturated fatty acids" as claimed in satisfaction of the written description requirement of 35 U.S.C. 112, first paragraph, but fails to present any description and/or disclosure of relevant identifying characteristics that would be supportive of establishing that Applicant was, in fact, in possession of the full scope of "retinoids" or "unsaturated fatty acids" presently claimed. While the instant disclosure provides adequate written description of those agents specifically named, it fails to provide description of any other compound(s)

that falls within the claimed genera such that these other members of the claimed genera could be immediately envisaged and/or readily identified. The idea that, in order to identify the other members of the genus, one of skill in the art would have to undertake extensive hit or miss testing to determine the full scope of the genus is clearly indicative of the fact that Applicant was, in fact, not in possession of the entire scope of compounds presently claimed. This is because Applicant cannot logically be in possession of that which he has yet to identify.

It has long been held that, when there is substantial variation within a genus, one must describe a sufficient variety of species *to reflect the variation within the genus*. Given that Applicant has placed essentially no limitation on the identity of the compounds within the claimed genus of retinoids or unsaturated fatty acids, the identification of the few species named fails to represent a variety of species that would reflect the substantial variation clearly present within the claimed genera such that it would have been clear that Applicant was, at least, in possession of the *full* scope of retinoids and/or unsaturated fatty acids as instantly claimed.

Considering the teachings provided in the specification as originally filed, Applicant has failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the entire genera of retinoids or unsaturated fatty acids for use in the claimed suspension preparation.

Accordingly, for these reasons, the claims are properly rejected under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement.

Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Present claim 10 is directed to a process for preparing said suspension as claimed in claim 1, which comprises (a) grinding solid particles of one or more salts of ascorbic acid in a dispersant until the average particle size is from 0.001 to 1000 μm, wherein said one or more salts of ascorbic are insoluble in said dispersant, and optionally adding said one or more oxidation-sensitive substances before, during or after said grinding or (b) grinding solid particles of one or more salts of ascorbic acid until the average particle size is from 0.01 to 1000 μm and suspending the ground particles in a dispersant wherein said one or more salts of ascorbic acid are insoluble and one or more oxidation-sensitive substances are optionally added to the dispersant before, during or after the suspension of the solid ascorbate particles.

In particular, it is unclear how the process of preparation recited in claim 10 is capable of forming a suspension as defined in claim 1 (i.e., a suspension comprising at least one oxidation-sensitive substance selected from carotenoids, retinoids and unsaturated fatty acids, and solid particles of one or more salts of ascorbic acid in a dispersant, wherein said one or more salts of ascorbic acid are insoluble) when the oxidation-sensitive substance is "optionally added" to the suspension. The phrase "optionally added" clearly indicates that the oxidation-sensitive substance may or may not be added to the dispersant. In the event that such a substance is omitted from the dispersant, the product that would then be formed would contain only a suspension of the solid particles of ascorbic acid and, therefore, would *not* be a suspension according to the claimed limitations of instant claim 1. Accordingly, it would appear that, in order to form a suspension commensurate with that defined in claim 1, the addition of the oxidation-sensitive substance is not optional, but rather required. Clarification is requested.

For these reasons, the claim fails to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and is, thus, properly rejected.

Claim Rejections - 35 USC § 102 (New Grounds of Rejection)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Betz et al. (WO 01/67896; 2001, in German), citing to U.S. Patent Application Publication No. 2003/0185877 (2003) for an English translation.

For the purposes of examination, U.S. Patent Application Publication No. 2003/0185877 A1 to Betz et al. (Published October 2, 2003) will be relied upon for an English translation of the WO 01/67896 reference relied upon as the basis for the present rejection. The '877 publication is the publication under 35 U.S.C. 122(b) of U.S. Patent Application No. 10/221,203, which is the U.S. National Stage (371) entry of PCT/EP01/02939, of which WO 01/67896 is the International WIPO Publication of the same and is, thus, expected to contain the same subject matter. Reliance upon this document is in accordance with the MPEP at §901.05, which states, "It is possible to cite a foreign language specification as a reference, while at the same time citing an English language version of the specification with a later date as a convenient translation if the latter is in fact a translation." For clarity of the record, Applicant is notified that the page and paragraph numbers cited herein the instant rejection refer to the '877 publication and not the '896 publication.

Betz et al. teaches an oily suspension of at least one water-soluble vitamin (p.1, para.[0001]), such as, e.g., ascorbic acid and salts thereof, such as sodium ascorbate (p.1, para.[0013]). Betz et al. teaches that the dispersing medium may comprise vitamin E and/or its derivatives (such as, e.g., alpha-, beta-, gamma- or delta-tocopherol, p.1, para.[0017]) used alone or in combination with other edible oils (such as, e.g., sunflower oil, palm oil, etc.; see p.1, para.[0016-0018]). Betz et al. discloses that the oily

suspensions comprise from 15-50% by weight of at least one water-soluble vitamin (p.2, para.[0034]) and may additionally comprise at least one other carotenoid (e.g., beta-carotene, lycopene, lutein, astaxanthin, etc.; p.2, para.[0037]) in an amount of 0.1-40% by weight of the total amount of the formulation (p.3, para.[0040]). Additional ingredients of the suspension may also include polyunsaturated fatty acids, such as, e.g., linoleic acid, linolenic acid, arachidonic acid, eicosapentaenoic acid, and docosahexanoic acid (p.3, para.[0048]) and/or lipid-soluble vitamins (in an amount of 15-50% by weight, see p.2, para.[0035]), such as, e.g., vitamin A (i.e., retinol) and derivatives, such as vitamin A acetate, vitamin A propionate or vitamin A palmitate (p.2, para.[0032]), as well as a dessicant (p.2, para.[0028-0030]). Betz et al. teaches a process for producing the suspension, comprising (a) grinding at least one water-soluble vitamin in an oil, preferably in at least one edible oil, until the average particle size is from 0.1-100 μm, or (b) grinding at least one water-soluble vitamin without using a continuous phase until the average particle size is from 0.1-100 μm and subsequently suspending the ground particles in an oil, preferably in an edible oil (p.1, para.[0010-0012]). Betz et al. teaches that the lipid-soluble vitamins and carotenoid compounds can be added to the suspension before, during or after the grinding process (p.3, para.[0042]). Disclosed advantages of the oily suspension are that the vitamins are insoluble in the oil and, thus, are protected from oxygen and moisture and cannot undergo any reactions with one another (p.3, para.[0054]). Betz et al. teaches that the suspensions are suitable to be added to human food and animal feed preparations, as well as cosmetic or pharmaceutical preparations (p.3, para.[0055], [0061] and [0071-0072]) and, when used as a feed additive in livestock nutrition, the suspensions are applied to or sprayed onto feed pellets, such as via loading the feed pellets with the oily suspension under reduced pressure (p.3, para.[0056-0058]).

Though Betz et al. discloses the protection of the water-soluble vitamin component and is silent as to the specific reduction in oxidation of the carotenoid, retinoid or unsaturated fatty acid compound as recited in instant claim 11), the preparation of the same compound as claimed via an identical process

using identical components is expected to necessarily have the claimed effect on reducing oxidation of the carotenoid, retinoid and/or unsaturated fatty acid component (as instantly claimed), whether recognized by Betz et al. or not. Products of identical composition cannot exert mutually exclusive properties when prepared under the same circumstances using identical components in overlapping amounts. Please reference MPEP §2112.

Conclusion

The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. Please reference U.S. Patent Application Publication No. 2002/0110599 to Auweter et al. ("Production of Solid Preparations of Water-Soluble Sparingly Water-Soluble or Water-Insoluble Active Compounds") and the English abstract of JP 11-056255 to Sakurada et al. ("Oil-Based Composition and Feed Added with the Same").

Rejection of claims 1-17 remains proper and is **maintained**.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

February 1, 2008

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER